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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,106	02/17/2004	James B. Dale	481112.410C1	8037

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EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,106	DALE, JAMES B.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27* is/are pending in the application.

4a) Of the above claim(s) *1,2,4-7,10,11 and 15-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,8,9,12-14 and 18-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02/17/04* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1) Acknowledgment is made of Applicant's preliminary amendment filed 01/03/07.

Election

2) Acknowledgment is made of Applicant's election filed 01/03/07 in response to the restriction requirement mailed 10/03/06. Applicant has elected species (D), hexavalent hybrid fusion polypeptide, and the Group A streptococcal serotype M2 species. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P § 818.03(a)).

Status of Claims

3) Claims 1, 3, 5 and 10 have been amended via the amendment filed 01/03/07.

Claims 1-27 are pending.

Claims 1, 2, 4-7, 10, 11 and 15-17 have been withdrawn from consideration as being directed to a non-elected species. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03. Claim 10, as amended, now belongs to the pleural hybrid fusion polypeptide species (B) and therefore is withdrawn from consideration.

Claims 3, 8, 9, 12-14 and 18-27 are under examination. A First Action on the Merits is issued on these claims. All of the Group A streptococcal M serotype species encompassed within the elected hexavalent hybrid fusion polypeptide species, in addition to the elected M2 species, i.e., M11, M22 and M28, have been examined together.

Information Disclosure Statement

4) Acknowledgment is made of Applicant's information disclosure statement filed 02/17/04. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgment is made of Applicants' raw Sequence Listing which has been entered 02/26/04.

Priority

6) The instant application is a continuation of application SN 09/151,409, filed 09/10/1998, *now US patent 6,716,433*, which claims priority to the provisional application 60/058,635, filed 9/12/1997.

Specification

7) The specification is objected to for the following reason(s):

(a) The first paragraph of the instant specification does not accurately recite the issued status of the prior application as indicated above in italicized letters under the section 'Priority'. Amendment to the specification is needed.

(b) The use of trademark recitation in the instant specification has been noted. For example, see line 9 on page 22: 'Gelvetol'. The recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification to make similar corrections to trademark recitations, wherever such recitations appear.

Double Patenting Rejection(s)

8) The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See e.g., *In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998)*; *In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993)*; *In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir, 1985)*; *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R 3.73(b).

9) Claims 3, 9, 12-14 and 18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3, 7, 9, 10 and 15 of US patent 6,716,433 ('433). Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in the co-pending application is encompassed within the scope of the instant claims.

Instant claims encompass a hybrid fusion polypeptide comprising a multivalent portion that comprises six immunogenic amino-terminal polypeptides of group A streptococcal M protein from six different Group A streptococcal serotypes wherein each of the at least six immunogenic amino-terminal polypeptides is at least 10 amino acids in length, and a carboxy-terminal reiterated immunogenic polypeptide, which is carboxy-terminal to the multivalent portion and is a reiteration of a polypeptide from the amino-terminal region of the multivalent portion, as claimed. At least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from Group A streptococcal serotype 11, 22, or 28, and the immunogenic polypeptides are joined by amino acids by a restriction enzyme site. The above-identified claims of the '433 patent encompass a recombinant fusion polypeptide comprising a multivalent immunogenic portion consisting of six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes and an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion which is a reiteration of the immunogenic amino-terminal polypeptide from the amino terminus of the multivalent immunogenic portion. At least one of the immunogenic amino-terminal polypeptides of the fusion polypeptide is from Group A streptococcal serotype 11, 22, or 28, and the immunogenic polypeptides are joined by amino acids by a restriction enzyme site. Clearly, claims 3, 7, 9, 10

and 15 of the '433 patent anticipate the instant claims.

10) Claims 22 and 23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 48 and 76 of the co-pending application 10/284,400. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claimed in the co-pending application is encompassed within the scope of the instant claims.

Claim 22 encompasses a composition comprising a pharmaceutically acceptable carrier and a hybrid fusion polypeptide comprising six immunogenic amino-terminal polypeptides of Group A streptococcal M protein from six different Group A streptococcal serotypes, each at least 10 (i.e., inclusive of 30) amino acids in length, and a carboxy-terminal immunogenic polypeptide carboxy-terminal to the multivalent portion which carboxy-terminal immunogenic polypeptide is a reiteration of a polypeptide from the amino terminal region of the multivalent portion. The open claim language 'comprising' in claim 22 permits the presence of one or more hybrid polypeptide(s) in the claimed composition. Claim 48 of the co-pending application 10/284,400 encompasses a composition comprising a pharmaceutically acceptable carrier and at least two hybrid polypeptides wherein one said hybrid polypeptide comprises six different immunogenic amino terminal peptides of Group A streptococcal M proteins M5, M6, M14, M19, M24 and M29, each comprising at least 30 contiguous amino acids wherein one of the immunogenic peptides located at the amino-terminal end of the hybrid polypeptide is reiterated at the carboxy-terminal end of the hybrid polypeptide. Therefore, claim 48 of the co-pending application anticipates the generic composition claimed in the instant claim 22. Claim 76 of the co-pending application anticipates claim 23 of the instant application.

This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

Rejection(s) under 35 U.S.C. § 112, First Paragraph (New Matter)

11) Claim 3 is rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 3 includes the limitation: 'fusion polypeptide, comprising .... a multivalent immunogenic portion ..... a carboxy-terminal ... immunogenic polypeptide, which is carboxy-terminal to the multivalent immunogenic portion and is a reiteration of a polypeptide from the amino-terminal region of the multivalent portion'. The recited 'immunogenic polypeptide which is carboxy-terminal to the multivalent portion' encompasses one that protects the immunogenicity of the multivalent immunogenic portion and one that does not. However, the description in the specification, as originally filed, is limited to a fusion polypeptide comprising a multivalent immunogenic portion *fused* to an immunogenic polypeptide carboxy-terminal to the multivalent immunogenic portion --which protects the immunogenicity of the multivalent immunogenic portion--. See first paragraph under 'Summary of the Invention'; and original claims 11, 5 and 1 from the parent application 09/151,409. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

12) Claim 25 is rejected under 35 U.S.C § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 25 includes the limitation: 'the pharmaceutically acceptable excipient, carrier, stabilizer or diluent comprises at least one of a buffer, antioxidant, carbohydrate, and chelating agent'. However, there is no descriptive support for this limitation in the instant specification, as originally filed. Paragraph [0046] of the instant specification under the section 'Formulation and Administration' describes that what is administered to a patient is a vaccinating agent in the form of a pharmaceutical composition comprising purified polypeptide in conjunction with

physiologically acceptable carriers, excipients, or diluents. This part of the specification describes that the preparation of such compositions entails combining the vaccinating agent, i.e., pharmaceutical composition, with stablilizers, excipients, buffers, antioxidants, carbohydrates and chelating agents. However, a 'pharmaceutically acceptable excipient, carrier, stabilizer or diluent' that 'comprises at least one of a buffer, antioxidant, carbohydrate, and chelating agent' as recited in the instant claim is not supported by the instant specification, as originally filed. Therefore, the above-identified limitations in the claims are considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

13) Claim 3 and those dependent therefrom are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 3, as amended, includes the limitations: 'a carboxy-terminal reiterated immunogenic polypeptide, which is carboxy-terminal to the multivalent portion and is a reiteration of a polypeptide from the amino-terminal region of the multivalent portion'. As amended, 'a carboxy-terminal reiterated immunogenic polypeptide, which is carboxy-terminal to the multivalent portion and is a reiteration of a polypeptide from the amino-terminal region of the multivalent portion' can be of any length, i.e., less than 10 amino acids-long, and can include any polypeptide from the unspecified amino-terminal 'region' of the multivalent portion. However, there is no descriptive support in the specification, as originally filed, for a hybrid fusion polypeptide comprising such a carboxy-terminal reiterated immunogenic polypeptide as recited. Therefore, the above-identified limitation(s) in the claim is considered to be new matter. *In re Rasmussen*, 650 F2d 1212 (CCPA, 1981). New matter includes not only the addition of

wholly unsupported subject matter but also, adding specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicant is respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

14) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

15) Claims 3, 8, 9, 12-14 and 18-27 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 3 is vague and indefinite in the limitation: amino-terminal 'region' of the multivalent portion, because it is unclear what is encompassed within the 'region'. Does this 'region' encompass amino-terminal half of the multivalent portion, amino terminus of the multivalent region, or a region of any size in between? Clarification/correction is requested.

(b) Claim 3 is further indefinite, confusing and/or redundant in the limitation: 'reiterated .... polypeptide .... is a reiteration of a polypeptide'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant delete the limitation 'reiterated' in line 7 of the claim.

(c) Claim 3 is indefinite and confusing in the limitation: 'a polypeptide from the amino-terminal region of the multivalent portion (see last two lines). Is this polypeptide one of the immunogenic amino-terminal polypeptides from part (a) of the claim that is at least 10 amino acids in length, or is this polypeptide of any length? Does this 'a polypeptide' include a part each of the immunogenic amino-terminal polypeptides from the amino-terminal region of the multivalent portion from part (a) of the claim? Clarification/correction is requested.

(d) Claim 22 lacks proper antecedent basis in the limitation: 'a hybrid fusion

polypeptide according to any one of claims'. Claim 22 depends from one of claims 1-3, each of which already includes the limitation of 'a hybrid fusion polypeptide'. For proper antecedent basis, it is suggested that Applicant replace the above-identified limitation with the limitation -- the hybrid fusion polypeptide--.

(e) Claim 23 is indefinite and incorrect in the limitation: 'further comprising with an adjuvant'. For the purpose of distinctly claiming the subject matter, it is suggested that Applicant delete the limitation 'with'.

(f) Claim 26 is indefinite because it has improper antecedent basis in the limitation: 'The fusion polypeptide according to claim 22'. Claim 26 depends from claim 22, which is drawn to a composition, but not to a fusion polypeptide.

(g) Analogous rejection applies to claim 27, which depends indirectly from claim 22.

(h) Claims 8, 9, 12-14 and 18-27, which depend directly or indirectly from claim 3, are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Remarks

16) Claims 3, 8, 9, 12-14 and 18-27 stand rejected.

17) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

18) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

19) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday

to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

March, 2007

S. DEVI, PH.D.
PRIMARY EXAMINER